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106TH CONGRESS
1ST SESSION

H. R. 2338

To require the Secretary of Health and Human Services to provide an individual who seeks to have a particular type of item or service to be covered benefit under the Medicare Program the option to meet with the Secretary in advance to develop a written agreement specifying the information necessary for the Secretary to make a national coverage determination under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

JUNE 24, 1999

Mr. RAMSTAD introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To require the Secretary of Health and Human Services to provide an individual who seeks to have a particular type of item or service to be covered benefit under the Medicare Program the option to meet with the Secretary in advance to develop a written agreement specifying the information necessary for the Secretary to make a national coverage determination under the Medicare Program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicare Coverage Information Decision Act of 1999".

SEC. 2. MEETINGS REGARDING COVERAGE DECISIONS.

(a) MEETINGS WITH THE SECRETARY.—

(1) IN GENERAL.—

(A) DEADLINE FOR MEETING.—In the case of a person who submits to the Secretary of Health and Human Services written notice that the person intends to seek a national coverage determination by the Secretary with respect to whether a particular type or class of items or services shall be covered under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Secretary shall meet with such person not later than 30 days after receiving the request.

(B) PURPOSE OF MEETING.—Subject to paragraph (3), the purpose of any meeting pursuant to paragraph (1) shall be to enter into a written agreement that describes the specific information the Secretary requires in order to make a national coverage determination with respect to the particular type or class of items or services under such title.

(2) CONTENT OF NOTICE.—A notice under paragraph (1) shall include the following descriptions:

(A) A description of the particular type or class of items or services proposed to be covered under such title.

(B) A description of the conditions for the use of the particular type or class of items or services.

(C) A description of the benefit categories for which the particular type or class of items or services is intended to be used.

(3) EXCEPTION.—If the Secretary determines that a national coverage policy determination is not appropriate or is premature for the particular class of items or services that is the subject of the meeting, the Secretary may decline to enter into an agreement.

(b) PROVISIONS REGARDING AGREEMENTS.—

(1) IN GENERAL.—In the case of an agreement entered into by the Secretary and such person under subsection (a), not later than 30 days after the date the agreement is entered into, the Secretary shall transmit the written agreement to such person. The written agreement shall be part of the administrative

record with respect to the national coverage determination of the particular type or class of items or services proposed by such person to be covered under such title.

(2) MODIFICATIONS.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), any agreement entered into under subsection (a) may not be modified.

(B) EXCEPTIONS.—Any such agreement may be modified in any of the follow manners:

(i) In the case of a proposed modification to the person by the Secretary, other than a determination under clause (ii), the person submits to the Secretary written notice that the person agrees to the modification.

(ii) Subject to subparagraph (C), the Secretary determines that a substantial scientific issue essential to determining whether the particular type of class of items or services is reasonable and necessary has been identified.

(C) SUBSTANTIAL SCIENTIFIC ISSUE.—A modification to an agreement by reason of a determination under subparagraph (B)(ii) shall be

in writing, and may only be made after the Secretary has provided to such person an opportunity to meet with the Secretary to discuss the scientific issue involved.

(c) TRADE SECRETS.—Subject to paragraph (2), any information reported to or otherwise obtained by the Secretary pursuant to this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall be considered confidential and may not be disclosed, except that such information may be disclosed to officers or employees of the Department of Health and Human Services in their capacity as employees in administering the medicare program under title XVIII of the Social Security Act.

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